



MRN: _____

Phone: 1-800-809-1265 Fax: 1-866-872-8920

DOB: _____

STANDARD Entyvio® (vedolizumab) PLAN OF TREATMENT FOR GASTROENTEROLOGY

Patient cannot receive Entyvio while receiving Tysabri® (Natalizumab) or other TNF

(Re) Certification Period From _____ to _____

NOTE: Patient may be ineligible to receive vedolizumab if receiving antibiotics for active infectious process, antifungal therapy, active fever and/or suspected infection, new-onset or deterioration neurological changes, and/or surgery.

1. Patient Name: _____ Height (inches): _____ Weight (lbs): _____

2. Allergies: _____

3. **DIAGNOSIS:** * Please complete the 2nd and 3rd digits to complete the ICD-10 code for billing

- K50.0** _____ Crohn's Disease (small intestine)
- K50.1** _____ Crohn's Disease (large intestine)
- K50.8** _____ Crohn's Disease (small & large intestine)
- K50.9** _____ Crohn's Disease, Unspecified
- K51.8** _____ Other Ulcerative (chronic) Colitis
- K51.5** _____ Left sided Ulcerative (chronic) Colitis
- K51.0** _____ Universal Ulcerative (chronic) Pancolitis
- K51.9** _____ Ulcerative Colitis, Unspecified
- Other **ICD-10 Code:** _____ **diagnosis description:** _____

4. **Pre-medications:** None **OR** Administered 30 minutes prior to infusion as selected:

*Suggest caution with use of Diphenhydramine due to 30 minute infusion time and safety risks with driving.

a) Acetaminophen: <input type="checkbox"/> 650mgs PO <input type="checkbox"/> 500mgs PO <input type="checkbox"/> 325mgs PO	b) Diphenhydramine: <input type="checkbox"/> 25 mgs PO, <input type="checkbox"/> 50mgs PO, <input type="checkbox"/> 25 mgs IVP, <input type="checkbox"/> 50mgs IVP or c) Alternate oral antihistamine to diphenhydramine: <input type="checkbox"/> Cetirizine 10 mg, <input type="checkbox"/> Loratadine 10 mg, Fexofenadine <input type="checkbox"/> 60mgs or <input type="checkbox"/> 180mgs d) Other: Methylprednisolone <input type="checkbox"/> 40mgs IVP <input type="checkbox"/> 125mgs IVP or other _____mgs IVP Famotidine: <input type="checkbox"/> 20mgs PO, <input type="checkbox"/> 40mgs PO, <input type="checkbox"/> 20mgs IVP, <input type="checkbox"/> 40mgs IVP
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e) Pre-medicate with other: _____

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Orders: Obtain weight each visit. **Vital signs at baseline and after completion then may discharge when infusion is complete.** Instruct patient/caregiver on medications and signs/symptoms of adverse reaction. Assess patient for response to therapy. Utilize existing central line for administration or initiate a peripheral IV with each infusion as needed. Sodium Chloride 0.9% flush 3-10 ml before, after, and as needed during the infusion. Follow infusion with Heparin 100 units/ml 1 – 5 ml per line type or to peripheral IV as required for multiple day treatments. Pump, tubing, 0.22 micron filter, and supplies needed to complete prescribed therapy. Pharmacist to perform clinical drug monitoring. **If adverse drug reaction occurs, utilize the ADVERSE DRUG REACTION GUIDELINES.**

Dose: Entyvio (vedolizumab) 300mgs per 250ml of Sodium Chloride 0.9% IV to infuse over at least 30 minutes

5. **Frequency:** _____ Induction orders to be completed at 0 week, 2 week, and 6 weeks, and then every 8 weeks thereafter
 _____ Orders every 8 weeks (maintenance).
 _____ Special Orders: _____

Lab orders with infusions: _____

6. **Physician's Signature:** _____ / _____ Date: _____
No Stamp Signatures (Dispense as written) (Substitution permitted)

Printed Physician's Name with Credentials: _____

7. Fax updated supporting clinical MD notes with each order renewal or change in orders
 Infusion order forms available at www.palmettoinfusion.com



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Guidelines for Prescribing Entyvio® (vedolizumab) FOR GASTROENTEROLOGY

(Required documentation with all initial referrals)

Patient Name: _____

Referral Date: _____

____ Include signed and completed **Plan of Treatment**. (MD must complete sections 1-7)
(Infusion order forms & Standard Adverse Reactions orders are available at www.palmettoinfusion.com under Agency/MD tab)

____ Include patient demographic information and insurance information. (Copy of insurance cards if available)

____ **Supporting clinical MD notes to include any past tried and/or failed therapies, intolerance, outcomes or contraindications to conventional therapy. Include any lab results and/or tests to support diagnosis.**

- Entyvio® is indicated for adult patients with moderately to severely active Ulcerative Colitis or Crohn’s Disease who have had an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids.

____ If patient is switching biological therapies, then MD must specify wash-out period prior to starting Entyvio® as specified of _____ weeks. Last known biological therapy: _____ and last date received: _____. (Include copy of last Entyvio® infusion record if available and currently on therapy)

____ Other as requested: _____

Pre-Screening: (TB and Hepatitis screening results must be available prior to start of therapy and within last 12 months.)

____ **Required TB screening results: PPD or QuantiFERON Gold Test.**
(* If screening results are positive or indeterminate, then a negative CXR result is required.)

____ **Required Hepatitis screening to include: Hepatitis B Surface Antigen results.**

** Warnings/Precautions: **Infections:** Entyvio® is not recommended in patients with active, severe infections until the infections are controlled. Serious infections have also been reported in patients treated with ENTYVIO, including anal abscess, sepsis (some fatal), tuberculosis, salmonella sepsis, Listeria meningitis, giardiasis and cytomegaloviral colitis. Patient should not have an active ongoing infection, signs or symptoms of malignancy, or invasive fungal infection. **Progressive Multifocal Leukoencephalopathy:** Although no cases have been observed in ENTYVIO® clinical trials, JCV infection resulting in progressive multifocal leukoencephalopathy (PML) and death has occurred in patients treated with another integrin receptor antagonist. A risk of PML cannot be ruled out. Monitor patients for any new or worsening neurological signs or symptoms. ENTYVIO® should be discontinued in patients with jaundice or other evidence of significant liver injury. Evaluation of immunizations should be completed prior to and live vaccines should not be given before or concurrently with Entyvio®. See full prescribing information.

Palmetto Infusion Services will complete insurance verification and submit all required clinical documentation to the patient’s insurance company for eligibility. Our office will notify you if any further information is required. We will review financial responsibility with the patient and refer them to any available Co-pay assistance as required. Thank you for the referral.

Please fax all information to 1-866-872-8920 or call 1-800-809-1265 for assistance.